IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: B. SCHINDLY, et al.	)	Examiner: M. CHORBAJI
	)	Art Unit: 1744
Serial No.: 09/314,497	)	
	)	Conf. No: 5279
Filed: May 19, 1999	)	
For: **FLOW THROUGH CHEMICAL INDICATOR FOR MEASUREMENT OF ACTIVE BIOCIDAL AGENTS**	)	
Date of Last Office Action: April 22, 2003	)	
Attorney Docket No.: MEDZ 2 01012	)	Cleveland, OH 44114 June 20, 2003

#21

SUPPLEMENTAL BRIEF

Mail Stop:
Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is an Appeal to the Board of Appeals and Interferences from the Final Rejection in the Office Action of May 22, 2002 and from the like non-final Rejection of April 22, 2003.

I. Real Party in Interest

This application is assigned to Steris Corporation. The Assignment is recorded in the U.S. Patent Office at Reel 009979, Frame 0741.

II. Related Appeals and Interferences

This application is not involved in any related appeals or interferences.

III. Status of the Claims

Claims 1-23 stand rejected as being unpatentable under 35 U.S.C. § 103 over Minerovic, et al. (US 5,997,814) in view of Ignacio, et al. (US 6,287,518).

Appellants appeal the rejection of all the pending claims. A correct copy of claims 1-23 appears in the Appendix attached hereto.

IV. Status of Amendments

The amendments filed on April 20, 2001, September 6, 2001, and February 1, 2002 have been entered. A Request for Reconsideration of July 22, 2002 has been considered. Amendment D of October 22, 2002 has been entered.

V. Summary of the Invention

The application discloses a single-use package **C** for holding a powdered decontaminant composition, such as reagents for forming peracetic acid (page 1, lines 3-8, page 14, lines 28-36). In the past, chemically treated paper strips have been placed in the most challenging areas of the sterilizer adjacent the sterilized objects to indicate if sterilization conditions, such as peracetic acid concentration and exposure time, were attained at the items. However, in flowing liquid sterilization, such strips are often lost and remain in the system for several cycles. Indicators that went through two or more cycles or which measured concentration remote from the items being sterilized are not a reliable record of whether the correct level of decontaminant was obtained at the item (page 3, lines 24-35).

Another difficulty is that multiple operators use sterilization systems. Because the instruments are typically rinsed before they are placed in the processor to remove excess bioload, they often look clean. When the cup is inserted into the well opening at the bottom, only the top is left showing. When one operator has an emergency and leaves the processor during the loading or unloading, it is difficult for the next

operator to guess whether the instruments are sterile instruments ready to be unloaded and used or used instruments ready to be sterilized.

In the present invention, this problem is overcome by placing an indicator **44** permanently located on a porous top portion **42** of the single-use package (page 8, lines 13-18; page 18, lines 20-22). The indicator exhibits a detectable change when mixed with a desired concentration of the decontaminant solution (page 15, lines 29-31), showing that the cup generated the prescribed quantity of peracetic acid. The package is placed in a well **16** of a decontamination apparatus **A** (page 6, lines 33-35, page 19, lines 8-10) where the peracetic acid is generated. Items to be sterilized are placed elsewhere in the decontamination apparatus, such as in a tray **14** (page 19, lines 8-10). After decontaminating the items, the spent package **C** is removed and the indication of decontaminant concentration provided by the indicator **44** is recorded (page 19, lines 18-21). The indicator clearly labels the spent package as spent.

* **VI. Issues**

1. Whether claims 1-7, 9-14 16, 17, and 22 are patentable under 35 U.S.C. §103 over Minerovic, et al. (U.S. Patent No. 5,997,814) in view of Ignacio, et al. (U.S. Patent No. 6,287,518).

2. Whether claim 8 is patentable under 35 U.S.C. §103 over Minerovic, et al. (U.S. Patent No. 5,997,814) in view of Ignacio, et al. (U.S. Patent No. 6,287,518).

3. Whether claim 15 is patentable under 35 U.S.C. §103 over Minerovic, et al. (U.S. Patent No. 5,997,814) in view of Ignacio, et al. (U.S. Patent No. 6,287,518).

4. Whether claim 18 is patentable under 35 U.S.C. §103 over Minerovic, et al. (U.S. Patent No. 5,997,814) in view of Ignacio, et al. (U.S. Patent No. 6,287,518).

5. Whether claim 19 is patentable under 35 U.S.C. §103 over Minerovic, et al. (U.S. Patent No. 5,997,814) in view of Ignacio, et al. (U.S. Patent No. 6,287,518).

6. Whether claim 20 is patentable under 35 U.S.C. §103 over Minerovic, et al. (U.S. Patent No. 5,997,814) in view of Ignacio, et al. (U.S. Patent No. 6,287,518).

7. Whether claim 21 is patentable under 35 U.S.C. §103 over Minerovic, et al. (U.S. Patent No. 5,997,814) in view of Ignacio, et al. (U.S. Patent No. 6,287,518).

8. Whether claim 23 is patentable under 35 U.S.C. §103 over Minerovic, et al. (U.S. Patent No. 5,997,814) in view of Ignacio, et al. (U.S. Patent No. 6,287,518).

VII. Grouping of the Claims

Each of independent claims, 1, 8, 15, 19, 20, 21, and 23 stand or fall separately and dependent claim 18 stands independently of the parent claim.

VIII. Argument

The New Statement of the Rejection

The Appellants note that the Examiner has reworded the rejection and that the rejection is now applied against claims 1-23. Although the rejection has been reworded, the Examiner has not withdrawn arguments presented in earlier Office Actions. Accordingly, this Brief retains the arguments to counter assertions previously made by the Examiner.

In the newly worded rejection, the Examiner states "Furthermore, Ignacio teaches that the location of the indicator can be placed anywhere on the single-use package (col. 9, lines 54-62) including on a porous portion of the top cover or the like". This statement is either very misleading or represents a misunderstanding of the term "package" as used in the two references. At column 9, lines 54-62, Ignacio is referring to the "package" in which an item to be sterilized is placed for sterilization and to maintain the sterilization afterward. Often, items to be sterilized are placed in a package which is permeable to the sterilant but impermeable to microbes. One common package is a Tyvec envelope, which permits liquid sterilants or steam to pass through them, but which has a pore size which is too small to be penetrated by airborne bacteria. After the item is sterilized, it remains in the Tyvec package

until it is ready to be used and is only opened at the usage site. At a surgical procedure, for example, the Tyvec package, whose exterior surface may have become infected with microbes, is opened by an assistant at the edge of the sterile field. The assistant carefully opens the package touching the outside only and holds it open for the surgeon inside the sterile field. The surgeon carefully removes the instrument from inside the package, touching only the instrument and the interior of the package. In this way, it is assured that the instrument remains sterile from the sterile processing until it is used. This Tyvec envelope or the like that Ignacio is addressing is at col. 9, lines 54-62. It should also be noted that in Ignacio's example of placing the chemical indicator on the package, the chemical indicator travels with the instrument to provide assurance at the point of use that the instrument was subject to a sterilization process. After all, if an attendant puts a dirty instrument in the Tyvec envelope in preparation for a sterilization process and it became somehow mixed among previously-sterilized Tyvec packaged instruments, all the packages would look just the same, but for the Ignacio chemical indicator.

In the Minerovic reference, the "package" is a cup which contains two compartments holding reagents which react in water to form the sterilant. This package does not hold the item to be sterilized. Rather, it is the source of the sterilant material.

Ignacio, at col. 9, lines 54-65, teaches only placing the chemical indicator on or in association with the item to be sterilized. It makes no suggestion and provides no motivation to attach a chemical indicator to the source of the sterilant material. After all, when the water is first introduced into the Minerovic cup or package, a very high concentration is initially produced. This concentration spike then becomes diluted as the sterilant is circulated to the items in the downstream sterilization chamber. As the Minerovic sterilant leaves the well, it goes to a heater **30** and then to the sterilant chamber **14**. Thus, items in the sterilization chamber are subject to sterilants of a different concentration, at a different temperature, and for different relative durations than the

sterilant supplying cup. Because the "packages" of Ignacio and Minerovic are different structures for different purposes, it is submitted that the above-quoted statement of the Examiner is highly misleading and that it does not support the Examiner's conclusion in the following sentence where the Examiner asserts that it would be obvious to modify Minerovic's package.

Issue 1

Claims 1-7, 9-14 16, 17, and 22 were rejected under 35 U.S.C. §103 over Minerovic, et al. (U.S. Patent No. 5,997,814) in view of Ignacio, et al. (U.S. Patent No. 6,287,518).

Claim 1 calls for a single-use package holding a powdered composition which forms a solution of an anti-microbial decontaminant, the package having a porous portion. An indicator on the porous portion exhibits a detectable change on exposure to a decontaminant in the solution.

1. The References do not Teach an Indicator on a Sterilant Package or Cartridge, as Claimed

As outlined below, Appellants maintain that placing an indicator in a sterilization chamber either on or along with items to be sterilized would not suggest to one of ordinary skill in the art that an indicator should be placed **elsewhere** in a sterilizer, in particular, made a part of a porous portion of a package holding a composition which forms an antimicrobial decontaminant.

As the Examiner acknowledges, **Minerovic, et al.** does not teach using an indicator which exhibits a detectable change on exposure to the decontaminant in the solution. Moreover, Minerovic, et al. provides no motivation for including such an indicator. As indicated in the background section of the Minerovic, et al. patent, a "two-compartment cup ensures sterilization with a reproducible, pre-measured dose of reagents" (col. 2, lines 1-3).

The Examiner asserts that Ignacio, et al. "teaches the use of an indicator, which exhibits a detectable change on exposure to a decontaminant in solution (col. 1, lines 47-52)" and incorrectly asserts that "the location of the indicator can

be placed any where on the single-use package (col. 9, lines 54-62)." (Office Action of November 6, 2002, page 5). Appellants respectfully traverse.

Ignacio makes no suggestion of placing an indicator on a single-use sterilant supplying package, or indeed on any package which holds a powdered composition for forming a solution of an anti-microbial decontaminant. Ignacio places the indicator on a sterile condition maintaining package which holds the sterilized item during sterilization and after. Ignacio teaches that the chemical indicator is used to monitor **the conditions to which the sterilized items are exposed**. (Col. 7, lines 25-29). Specifically, Ignacio states that the indicator composition is used to "monitor a peracetic acid liquid phase sterilization process to determine whether the sterilization process meets pre-determined parameters, e.g., **exposure** temperature, **exposure** peracetic acid concentration, and **exposure** time." Id., emphasis added.

Ignacio teaches that the indicator should be **close to the items being sterilized**. (col. 9, lines 54-65). For example, the monitor of Ignacio may be "attached as a label to the item to be sterilized" or "used as a masking tape to seal a package containing an item to be sterilized," "included in the sterilization chamber along with the items to be sterilized," or placed within a vapor-permeable package or wrap which holds the item to be sterilized. Id. All of these locations place the indicator where it will be exposed to the same or substantially the same conditions as the item to be sterilized to ensure that the indicator provides a true measure of the process conditions which the item experienced. Thus, it is clear that Ignacio does not teach that the indicator should be placed well away from the item to be sterilized, such as anywhere on a single-use sterilant source package where sterilant concentrations as the reagents mix with water to create the sterilant solution are much higher than at the items or elsewhere in the system, as asserted by the Examiner.

The Examiner further asserts that "the claims in the application recite 'an indicator on the porous portion' without providing a specific location. . . . If the indicator is put on

the surface 72, then it is not remote from the item." (Office Action of May 22, 2002). A review of Figures 2 and 4 of the application reveals this statement is clearly in error. The "surface 72," referred to by the Examiner is an inner cup peripheral wall (page 9, line 25). It is thus **inside** the self-contained package **C**, as shown clearly in Figure 4. As shown in Figure 2, the package **C** is placed in a well **16** of a microbial decontamination system, spaced from the tray **14**, where the items are placed. It is clear that all porous portions **72**, **98**, and **42** of the package referred to by the Examiner are well away from the item, and peripheral wall **72** particularly so.

Moreover, the indicator is read visually. If the indicator were placed in the interior of the sterilant package it would be impossible or virtually impossible to see and read it. The combination would render the indicator unusable for its intended use.

The Examiner also asserts that it is routine experimentation to place the indicator as close or as far from the item to be sterilized. (Office Action, May 22, 2002, page 2). Appellants maintain that, to the contrary, generations of experimentation have shown that the indicator must be placed in a position where it experiences as close to the identical exposure conditions as the items being sterilized to such a degree that it is now the conventional wisdom in the art.

The Examiner further asserts that in the response of February 1, 2002, the Appellants argued that Ignacio does not place a monitor on its sterilant source. The Examiner further asserts that "the claims in the [09/314,497] application do not mention of placing a monitor on the sterilant source." (Office Action of May 22, 2002, page 3).

Appellants acknowledge having referred generally in the response to the claimed "single-use package holding a powdered composition which forms a solution of an anti-microbial decontaminant" as a "sterilant source" for convenience. Although claim 1 does not literally state "placing a monitor on a sterilant source," the claim clearly calls for an indicator on a porous portion of "a single-use package holding a powdered composition which forms a solution of an anti-microbial

decontaminant." The generalization "sterilant source" should clearly have been understandable as referring to the "single-use package holding a powdered composition which forms a solution of an anti-microbial decontaminant" referred to in the same paragraph of the response (Amendment of January 1, 2002, pages 6-7). Thus, it is clear that the Examiner's rejection, based on a narrow reading of the Appellants description of the claim limitations in this way, cannot be sustained.

Further, the **function** of the indicator of Ignacio, et al., that of "insuring proper concentration level of the sterilant" (as inferred by the Examiner) cannot be read as describing the **location** of the indicator.

The Examiner asserts that "it would have been obvious to one of ordinary skill in the art to place the indicator [of Ignacio] close or far (**in the sterilization chamber** close to the source of the sterilant) from the item to be sterilized." (Advisory Action, August 1, 2002, emphasis added). However, as shown in Figures 1 and 2, Minerovic's cartridge **C** is not placed **in a sterilization chamber with the items**. Unlike the vapor sterilization systems referred to by Ignacio, where the source of sterilant may be an inlet pipe to the sterilizer chamber, Minerovic's sterilant is in the form of a concentrate, which is placed in a well **16**, away from the receiving region **14** where sterilization takes place.

The Examiner further states that "whether the indicator is placed close to the source of sterilant or far from the source of sterilant is a routine experimentation based on the range of possibilities for placing the indicator provided by Ignacio." (Advisory Action, August 1, 2002, emphasis added).

Appellants maintain that the "range of possibilities" provided by Ignacio all emphasize placing the indicator in a sterilization chamber, close to the item. Although unstated, the object of this placement is clearly to ensure that the indicator is subjected to the same sterilization conditions as the item. Appellants submit that routine experimentation would **not** lead one of ordinary skill in the art to place an indicator on a cartridge holding a sterilant concentrate where sterilant concentrations may be expected to be **unlike** those experienced by the item.

2. There in No Motivation To Combine Ignacio with Minerovic

The Examiner asserts that "one skilled in the art would have been motivated to combine Minerovic et al with Ignacio et al in order to insure that sterilization processes are effective and meet certain pre-determined sterilization parameters (Ignacio et al, col.1, lines 17-20 and lines 62-67)." (Office Action of November 6, 2001, page 5). Appellants respectfully traverse.

Appellants maintain that the combination is also improper because there is no motivation for combining the references of Minerovic, et al. and Ignacio, et al. The burden is on the Patent and Trademark Office to establish a prima facie case of obviousness. In re Rijckaert, 9 F.3d 1531, 1532 (Fed. Cir. 1993). In so doing, the Examiner is required to make a factual determination as set forth in Graham v. John Deere Co., 383 U.S. 1 (1966), and to provide a reason why one of ordinary skill in the art would have been led to modify the prior art to arrive at the claimed invention. The motivation must stem from some teaching, suggested or inferred in the prior art as a whole or knowledge generally available to one having ordinary skill in the art. Uniroyal Inc. v. Rudkin-Wiley, 837 F.2d 1044 (Fed. Cir. 1988); In re Rijckaert, 9 F.3d at 1532.

Appellants maintain that there is no teaching in Ignacio or Minerovic of placing an indicator on a single use package, such as that of Minerovic, which is well away from the sterilization process. The chemical environment in the region of the package **C** of Minerovic cannot be assumed to reflect the process conditions in the sterilizer.

Appellants maintain that the combination of Minerovic, et al. and Ignacio, et al. is improper because Ignacio, et al. teaches away from the claimed invention. A reference which leads one of ordinary skill in the art away from the claimed invention cannot render it obvious under 35 U.S.C. §103. Dow Chemical Company v. American Cyanamid Company, 816 F.2d 617 (Fed. Cir. 1987).

Ignacio, et al. teaches that the indicator should be close to the item, where it can measure the process conditions experienced by the item. (col. 9, lines 54-62). Ignacio clearly teaches away from exposing an indicator to an environment which may not accurately reflect process conditions at the sterilized item. Thus, one of ordinary skill in the art would not be motivated to place an indicator well away from the item, in conditions which could not necessarily be expected to reflect those within the sterilizer. Placing the indicator on a sterilant concentrate package would defeat the object of Ignacio, which is to reproduce, as closely as possible, the environment experienced by the item being sterilized.

Further, Appellants maintain that the combination of Minerovic, et al. and Ignacio, et al. is improper because it does not arrive at the presently claimed invention. The teaching of Ignacio, et al. might suggest to one of ordinary skill in the art to place an indicator in the tray **14** of Minerovic, but not well away from the items being sterilized, such as on Minerovic's cartridge **C**.

Moreover Appellants maintain that the combination of Minerovic, et al. and Ignacio, et al. is improper because neither Minerovic, et al. nor Ignacio, et al. recognize the problem that Appellants sought to solve. Fundamental to a determination of obviousness is a consideration of the problem sought to be solved by the inventor. Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 678-79, 7 U.S.P.Q.2d 1315, 1318 (Fed. Cir. 1988). "The problem confronted by the inventor must be considered in determining whether it would have been obvious to combine references in order to solve that problem." Id.

The Examiner asserts that in the response of February 1, 2002, the Appellant argued that Ignacio does not place a monitor on its sterilant source, but that

> the claims in the application do not mention of placing a monitor on the sterilant source. However, Ignacio's indicator insures proper concentration level of the sterilant during the process of sterilization. (Office Action of May 22, page 3).

The Appellants submit that the Examiner has failed to recognize the problems sought to be solved by the Appellants. The

Examiner infers that it does not matter where the indicator is placed as long as sterilization is insured. The Examiner fails to recognize the problem of losing indicators and the problem of having an indicator go through a cycle multiple times and thus giving a false assurance of sterility (specification, page 3, lines 24-35).

Moreover, an indicator on the top of the cartridge in the well provides an instant indicator if the cartridge is new or used. With Ignacio's manual placement of a separate indicator by the items to be sterilized, one needs to run an entire cycle to find out that someone left a used cartridge in the well and that the instruments are not ready for use after all. If the operator erroneously omits the step of placing the indicators near the items (and human error happens), there is no visual indication of a failed cycle and the rinsed but unsterilized instruments may be used on the next patient.

Neither Minerovic, et al. nor Ignacio, et al. recognizes the problem of losing indicators, the problem of having an indicator go through a cycle multiple times and the problem of operators who forget to add an indicator. Ignacio's indicators may get lost or transported along with the item to the storage area after removal. Or, through operator error or inadvertence, may not be removed and undergo several more sterilization cycles. There is no way of knowing for certain, whether the indicator of Ignacio has undergone several sterilization cycles before being examined.

Appellants have found that by placing the indicator on the single-use cartridge, problems such as these are virtually eliminated. First, the empty cartridge has to be removed before it can be replaced by a fresh cartridge, so there is the assurance that when the cartridge is replaced, the indicator will be removed from the sterilizer, and will not go through several sterilization cycles before being evaluated. Second, the relatively large cartridge is retained in the well, and thus the indicator is not likely to be washed away and lost.

Third, because the indicator is not attached to the item or associated packaging, it will not be sent off to the item storage room along with the sterilized item without review. The operator has a ready record which can be attached to the

sterilization system printout and kept for future verification that the cycle was effective.

Accordingly, it is submitted that Ignacio fails to teach or fairly suggest (and indeed, teaches away from) placing a sterilization indicator on the sterilant generating package of Minerovic, much less on the claimed portion of the package.

Appellants respectfully request that the Examiner's rejection of claim 1, and claims 2-7, 9-14, 16, 17, and 22 dependent therefrom, be reversed.

Issue 2

Claim 8 was rejected under 35 U.S.C. §103 (a) over Minerovic, et al. (U.S. Patent No. 5,997,814) in view of Ignacio, et al. (U.S. Patent No. 6,287,518).

Claim 8 calls for the indicator to be on the top cover of the single use package for holding the dry antimicrobial forming composition.

Appellants maintain that Ignacio provides no motivation for locating a sterilization monitor remote from the sterilized item, at which remote location it would not necessarily be expected to be a reliable indicator that the item was sterilized.

Appellants further maintain that the problem sought to be solved was not recognized by Ignacio or Minerovic. The positioning on the top cover allows the operator to determine, immediately on examination of the cartridge, still in the well, whether the package successfully generated a minimum dose of sterilant. If the cartridge indicator indicates a fail, the items need not be removed from the tray (specification, col. 19, lines 18-24), avoiding potential contamination of the operator. Conversely, at the beginning of a cycle, this location also solves the problem of assuring that the single use package received in the well **16** is a new package and has not been previously used. Ignacio has no recognition of these problems and provides no suggestion as to how they might be solved.

Indeed, Ignacio makes no suggestion of placing chemical indicators anywhere except with the items being sterilized, such as on a porous "package" which holds the sterilized item. Analogously, Ignacio makes no suggestion that a chemical indicator can be used to indicate whether an antimicrobial agent supplying cup functioned properly.

Accordingly, Appellants respectfully request that the Examiner's rejection of claim 8 be reversed.

Issue 3

Claim 15 was rejected under 35 U.S.C. §103 as unpatentable over Minerovic, et al. (U.S. Patent No. 5,997,814) in view of Ignacio, et al. (U.S. Patent No. 6,287,518).

Claim 15 calls for a package for holding an antimicrobial concentrate which forms an antimicrobial solution when mixed with water. An indicator on a porous portion of the package, which is permeable to the generated solution but not to the concentrate, exhibits a detectable color change when exposed to a preselected minimum concentration of the decontaminant in the solution for a preselected minimum period of time to indicate the formulation of an anti-microbial solution capable of effecting anti-microbial decontamination.

Appellants submit that Ignacio teaches away from placing an indicator on a porous portion of a package which releases a concentrate for forming a decontaminant. As the concentrate is first mixed with water, the concentration will be at its maximum. The concentration will then be diluted as the concentrate becomes mixed with all of the water in the system and distributed throughout the system. Thus, it would not be obvious to one of ordinary skill in the art to place an indicator so close to the concentrated decontaminant where an accurate measure of concentration of decontaminant to which the item is exposed could not be assumed to be made. Ignacio does not teach or fairly suggest placing a chemical indicator in a location where those of ordinary skill in the art would expect it to sense significantly different antimicrobial agent concentrations than are seen by the items being sterilized.

Moreover, claim 15 calls for the indicator to be positioned to be on a porous portion that is impermeable to the concentrate. The Examiner asserts that Ignacio teaches placing the indicator interior to the package where it would be in direct contact with one component of the concentrate. Placing the Ignacio color change indicator in with one of the Minerovic's components during shipping and storage could alter the color of the indicator making the validity of any read out questionable.

Accordingly, the Appellants respectfully request that the Examiner's rejection of claim 15 be reversed.

Issue 4

Claim 18, which calls for the package of claim 17, wherein the indicator includes crystal violet, was rejected under 35 U.S.C. §103 as unpatentable over Minerovic, et al. (U.S. Patent No. 5,997,814) in view of Ignacio, et al. (U.S. Patent No. 6,287,518).

The Appellants have found this indicator particularly useful because of its time dependent color change, i.e., it shows a marked change color over the time period a typical sterilization cycle at suitable sterilant concentrations and it is less sensitive to pH than other indicators (page 17, line 34-page 18, line 2).

Ignacio mentions crystal violet lactone as one of an extensive list of different dyes, without drawing particular attention thereto. Anticipation does not result when one skilled in the art would have to chose judiciously from a series of possible combinations. In re Sivaramakrishnan, 213 U.S.P.Q. 441 (CCPA 1982).

It is submitted for this reason, and for the reasons given in Issue 1 above, with respect to claim 1, that claim 18 is patentable over the references of record.

Accordingly, Appellants respectfully request that the Examiner's rejection of claim 18 be reversed.

Issue 5

Claim 19 was rejected under 35 U.S.C. §103 as unpatentable over Minerovic, et al. (U.S. Patent No. 5,997,814) in view of Ignacio, et al. (U.S. Patent No. 6,287,518).

Claim 19 calls for an anti-microbial system with a well for receiving a single use package. The package includes a porous portion affixed to a cup inlet. An indicator on the porous portion exhibits a detectable change on exposure to a decontaminant in the solution. Recirculating anti-microbial solution passes over the indicator.

Appellants maintain that Ignacio does not teach or fairly suggest the placement of chemical indicators in areas displaced from the items being sterilized, which areas could not necessarily be expected to see the same exposure conditions as the items to be sterilized. To the contrary, the placement of the indicators described in Ignacio at column 9, lines 54-65 all place indicators where they will be assured of experiencing substantially the same exposure conditions (column 7, lines 25-29) as the items being sterilized. Ignacio provides no motivation to provide an indicator at the mixing well where antimicrobial concentrate is mixed with water to form an antimicrobial solution.

Accordingly, the Appellants respectfully request that the Examiner's rejection of claim 19 be reversed.

Issue 6

Claim 20 was rejected under 35 U.S.C. §103 as unpatentable over Minerovic, et al. (U.S. Patent No. 5,997,814) in view of Ignacio, et al. (U.S. Patent No. 6,287,518).

Claim 20 calls for a flow through package for releasing an anti-microbial composition into a flowing liquid. The package includes a layer of porous material spanning the inflow or outflow openings. An indicator on the porous material layer changes color in response to contact with the anti-microbial solution, a degree of color change varying in accordance with (i) a concentration of an anti-microbial agent in the solution contacting the indicator, and (ii) a duration that the solution contacts the indicator such that the degree of

color change of the indicator is indicative of duration of contact and the concentration of the anti-microbial agent in the contacting solution.

Appellants maintain that the references of record do not fairly suggest such a system. The **Minerovic, et al.** patent provides no motivation for employing an a indicator in the sterilization system shown in Figure 1 of the patent. It is assumed that the reproducible, premeasured dose will ensure sterilization.

Ignacio, et al. does not suggest putting an indicator on a porous portion of a package for releasing an anti-microbial composition, much less the claimed placement on the inflow or outflow opening. Rather, the indicator is placed on or close to a medical instrument.

Appellants maintain that one skilled in the art would not be motivated, in view of Ignacio, to place an indicator at the source of the concentrate, where it could not necessarily be expected that the concentration to which it is exposed will be identical to that to which the items to be sterilized are exposed. Ignacio suggests placing an indicator on packaging which holds items that are the recipient of an antimicrobial solution or even placing the indicator in such a package in conjunction with packaged items, all of which are to be the recipient of such fully diluted, antimicrobial solution. Ignacio makes no suggestion of placing an indicator at the package which contains and is the source of the antimicrobial concentrate. Accordingly, it is submitted that claim 20 distinguishes patentably and unobviously over the references of record.

Accordingly, Appellants respectfully request that the Examiner's rejection of claim 20 be reversed.

Issue 7

Claim 21 is directed to a method in which water is flowed through a cartridge that contains a composition to form decontaminant solution from the composition and water. The cartridge includes a porous portion which is impregnated with an indicator.

Appellants maintain that the reference of record would not motivate one of ordinary skill in the art to impregnate a porous portion of a cartridge with an indicator, as claimed. The cartridge **C** of Minerovic does not include an indicator. Ignacio suggests placing indicators near items which are the recipient of already diluted decontaminant solutions, but provides no motivation to place an indicator at the source where concentrations may be expected to reach higher levels. To the contrary, it is submitted that Ignacio teaches against placing an indicator at the antimicrobial source in favor of placing the indicator in locations where it will be assured of experiencing the same exposure temperature, the same exposure peracid concentration, and the same exposure time as the items to be treated (column 7, lines 25-29).

Accordingly, Appellants respectfully request that the Examiner's rejection of claim 20 be reversed.

Issue 8

Claim 23 calls for an anti-microbial system which includes a well that receives a single-use package in the form of at least one cup which holds an anti-microbial source for forming an anti-microbial solution when mixed with water. The package includes a porous portion which is permeable to water and the anti-microbial solution and an indicator carried on the porous portion which exhibits a detectable color change upon exposure to a decontaminant in the anti-microbial solution. A source of water is connected with an inlet to the well and a microbial decontamination chamber is connected with an outlet from the well by a fluid line. Thus, the well is displaced from the decontamination chamber and the claim calls for the indicator to be in the well. Presumably, additional indicators similar to Ignacio's would be in the decontamination chamber, but this is neither required nor prohibited by claim 23. The package of Minerovic has no indicator. Ignacio, at col. 9, lines 54-65 teaches that an indicator should be placed in the sterilization chamber, such as being attached as a label to the item to be sterilized or used as a masking tape to seal a porous "package" containing the item to be sterilized. When the Ignacio indicator

is attached to an individual item or its packaging, it provides assurance that the associated item has been subject to the appropriate conditions for sterilization. This much quoted section of Ignacio provides no motivation to remove the indicator from the sterilization chamber and position it in another location in the sterilizer, much less the well or other location which receives and dilutes the concentrated sterilant and which distributes it in its diluted form to the sterilization chamber.

Because Ignacio provides every motivation to keep the indicator in the sterilization chamber and provides no motivation to move the indicator from the sterilization chamber to the well, much less provides any suggestion of connecting the indicator to a source of sterilant concentrate, it is submitted that claim 23 distinguishes patentably and unobviously over the references of record.

IX. Summary

For the reasons set forth above and the more detailed discussion of the reasons for the patentability of each of the independent claims set forth in the responses of April 20, 2001, February 1, 2002, and July 22, 2002, Appellants respectfully request the Board of Appeals reverse each rejection of the Examiner.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this **SUPPLEMENTAL BRIEF (x3)** in connection with U.S. Patent Application **Serial No. 09/314,497** is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 20th day of June, 2003.

Hilary McNulty

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: B. SCHINDLY, et al.	)	Examiner: M. CHORBAJI
Serial No.: 09/314,497	)	Art Unit: 1744
Filed: May 19, 1999	)	Conf. No: 5279
For: **FLOW THROUGH CHEMICAL INDICATOR FOR MEASUREMENT OF ACTIVE BIOCIDAL AGENTS**	)	
Date of Last Office Action: April 22, 2003	)	
Attorney Docket No.: MEDZ 2 01012	)	Cleveland, OH 44114 June 20, 2003

APPENDIX

1. A single-use package holding a powdered composition which forms a solution of an anti-microbial decontaminant when mixed with water and for releasing the composition when the package is opened or when the composition dissolves and passes through a porous portion of the package, the package comprising:

a porous portion which is impermeable to the powdered composition but is permeable to water and to the solution; and,

an indicator on the porous portion which exhibits a detectable change on exposure to the decontaminant in the solution.

2. The package of claim 1, further including:

a first compartment for receiving a first component of the composition; and,

a second compartment for receiving a second component of the composition, the porous portion, first compartment, and second compartment configured for forming a fluid flow path for the decontaminant solution through the package.

3. The package of claim 2, further including:

an outer, first cup including a first peripheral wall with an opening at an end, the first peripheral wall being at least selectively water transmissive;

an inner, second cup including a second peripheral wall, the second peripheral wall having a detachable base, the first and second cups being configured such that the second peripheral wall abuts and is connected to the first cup adjacent the end of the first peripheral wall;

a top cover covering the opening in the first cup, such that the first compartment is defined in the first cup and the second compartment is defined in the second cup.

4. The package of claim 22, wherein the first peripheral wall includes a region which is formed from a first material which is impermeable to the first component but is permeable to water and to solutions containing dissolved components.

5. The package of claim 3, wherein the first cup peripheral wall includes a side and a base, and wherein the base is detachable from the side.

6. The package of claim 22, wherein the water permeable portion of the second peripheral wall includes a region which is formed from a second material which is impermeable to the first and second components but is permeable to water and to solutions containing dissolved components.

7. The package of claim 6, wherein the second peripheral wall defines a hemisphere and is formed from the second material.

8. A single use package for holding a dry composition which forms an anti-microbial solution when mixed with water, the package comprising:

a side wall;

a bottom wall across a lower portion of the sidewall;

a top cover across an upper portion of the side wall, the top cover defining a porous portion which is impermeable to the dry composition but is permeable to water and to the solution; and

an indicator on the top cover which exhibits a detectable change on exposure to the anti-microbial solution.

9. The package of claim 1, wherein the porous portion is formed from a material selected from the group consisting of non-woven polypropylene web, woven polypropylene, woven polyethylene, non-woven polyethylene, nylon, rayon, rigid porous media, porous plastic, mesh, and combinations thereof.

10. The package of claim 2, wherein the decontaminant includes peracetic acid and the first component includes acetylsalicylic acid and the second component includes sodium perborate.

11. The package of claim 1, wherein the indicator includes an oxidizable species which changes color on prolonged contact with the solution.

12. The package of claim 1 wherein the indicator is specific for the decontaminant.

13. The package of claim 1, wherein the indicator is less sensitive to pH than to the decontaminant.

14. The package of claim 1, wherein the indicator is impregnated into the porous portion in the form of an ink.

15. A package for holding an anti-microbial concentrate which forms an anti-microbial solution when mixed with water, the package releasing anti-microbial concentrate at a selected time in an anti-microbial cycle, the package comprising:

a porous portion which is impermeable to the anti-microbial concentrate but is permeable to water and to the solution; and

an indicator on the porous portion which exhibits a detectable color change when exposed to a preselected minimum concentration of a decontaminant in the anti-microbial solution for a preselected minimum period of time to indicate the formulation of an anti-microbial solution capable of effecting anti-microbial decontamination.

16. The package of claim 1, wherein the decontaminant is peracetic acid and the indicator provides a detectable color change when the peracetic acid is at a concentration of about 900 ppm or above for a preselected period of time.

17. The package of claim 1, wherein the decontaminant is peracetic acid and the indicator is selected from the group consisting of crystal violet, bromocresol green, bromothymol blue, bromothymol green, methyl purple, and combinations thereof.

18. The package of claim 17, wherein the indicator includes crystal violet.

19. An anti-microbial system comprising:

a single use package;

a well for receiving the single use package, the package including:

at least one cup which holds an anti-microbial concentrate, the cup including an inlet,

a porous portion affixed to the cup inlet which is permeable to water and to an anti-microbial solution formed from the anti-microbial concentrate and the water, and

an indicator on the porous portion which exhibits a detectable change on exposure to a decontaminant in the solution;

a source of water connected with the well for mixing with the anti-microbial concentrate and forming the anti-microbial solution;

a microbial decontamination chamber connected with the well for receiving the anti-microbial solution, the well, the

porous region, and the chamber forming a recirculating fluid flow path for the anti-microbial solution, whereby the recirculating anti-microbial solution passes over the indicator.

20. A package for releasing an anti-microbial composition into a flowing liquid, the package comprising:

a side wall having a first opening at a first end and a second opening at a second end such that the liquid flows through the first opening into the package and out through the second opening;

a layer of porous material spanning one of the first and second openings such that the liquid flows through the porous material layer;

an anti-microbial source disposed within the package for releasing the anti-microbial composition into the flowing liquid to form an anti-microbial solution;

an indicator on the porous material layer which changes color in response to contact with the anti-microbial solution, a degree of color change varying in accordance with (i) a concentration of an anti-microbial agent in the solution contacting the indicator, and (ii) a duration that the solution contacts the indicator such that the degree of color change of the indicator is indicative of duration of contact and the concentration of the anti-microbial agent in the contacting solution.

21. A method comprising:

flowing water through a cartridge containing a composition to form a decontaminant solution from the composition and the water, the cartridge including a porous region impregnated with an indicator, the indicator exhibiting a preselected detectable change when contacted with a decontaminant solution and at a concentration of a decontaminant in the solution sufficient to effect decontamination of items;

circulating the decontaminant solution in a fluid flow path comprising a microbial decontamination chamber, in which the items to be decontaminated are positioned, and the porous region;

examining the indicator for the detectable change.

22. The package of claim 2, wherein the package further includes:

an outer, first cup including a first peripheral wall with an opening at an end, the first peripheral wall being at least selectively water transmissive;

an inner, second cup including a second peripheral wall, the second peripheral wall having a water permeable portion, the first and second cups being configured such that the second peripheral wall abuts and is connected to the first cup adjacent the end of the first peripheral wall;

a top cover covering the opening in the first cup, such that the first compartment is defined in the first cup and the second compartment is defined in the second cup.

23. An anti-microbial system comprising:

a well for receiving a single use package, the package including:

at least one cup which holds an anti-microbial source for forming an antimicrobial solution when mixed with water,

a porous portion connected to the cup and being permeable to water and to an anti-microbial solution formed from the anti-microbial source and the water, and

an indicator carried on the porous portion which exhibits a detectable change on exposure to a decontaminant in the anti-microbial solution;

a source of water connected with an inlet to the well for mixing with the anti-microbial source and forming the anti-microbial solution;

a microbial decontamination chamber for receiving the anti-microbial solution from an outlet from the well;

a fluid line connecting the chamber with the well outlet;

the well, the fluid line, and the chamber forming a recirculating fluid flow path for the anti-microbial solution through the porous region, whereby the recirculating anti-microbial solution passes over the indicator.